IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

TERI ARCOREN, Plaintiff, vs. DEPUY SYNTHES SALES, INC. d/b/a DEPUY SYNTHES JOINT RECONSTRUCTION; DEPUY ORTHOPAEDICS, INC; DEPUY INTERNATIONAL LIMITED; JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON INTERNATIONAL; MEDICAL DEVICE BUSINESS SERVICES, INC.; DEPUY INC.; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES, INC.; DEPUY IRELAND UNLIMITED COMPANY; DEPUY SYNTHES JOHNSON & JOHNSON IRELAND LTD. JOHNSON & JOHNSON; and DEPUY MITEK, INC., Defendants.	)	Case. No.: **COMPLAINT** **JURY TRIAL DEMANDED**

COMES NOW Plaintiff TERI ARCOREN, who by and through the undersigned counsel, hereby submits this complaint against the above-named defendants, her relief deemed just and proper arising from the injuries of Plaintiff, as follows:

PARTIES

1. At all times relevant hereto, Plaintiff TERI ARCOREN was a citizen of the State of South Dakota.

2. Defendant DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction ("DSS") is and, at all times relevant, was a corporation organized and existing under the laws of

the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of South Dakota by selling and distributing its products in South Dakota. Upon information and belief, DSS is a division and/or subsidiary of DePuy Orthopaedics, Inc. ("DOI"). DSS is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

3. DSS designs, makes, imports, distributes, sells and/or offers for sale total knee replacement prostheses, including the SIGMA Device. DSS was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the SIGMA Device, as well as monitoring and reporting adverse events related to the SIGMA Device.

4. Defendant Medical Device Business Services, Inc. ("Device Business Services") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of South Dakota by selling and distributing its products in South Dakota, with a registered office in South Dakota. Device Business Services is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

5. Defendant DePuy Orthopaedics, Inc. ("DOI") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of South Dakota by selling and distributing its products in South Dakota, with a registered office in South Dakota. DOI is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

6. At all times relevant, DOI and Device Business Services were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, packaging, labeling and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the SIGMA Device, as well as monitoring and reporting adverse events associated with SIGMA. DOI and Device Business Services participated in the decision-making process and response of the Defendants, if any, related to SIGMA adverse events and/or MAUDE reports.

7. Defendant DePuy Synthes Products, Inc. ("DSP") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of South Dakota by selling and distributing its products in South Dakota.

8. DSP is division of DOI. DSP is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

9. Defendant DePuy Synthes, Inc. ("DS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and at all relevant times was doing business in the State of South Dakota by selling and distributing its products in South Dakota.

10. Defendant DePuy Mitek, LLC ("DM") is and, at all times relevant, was a limited liability company organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of South Dakota by selling and distributing its products

in South Dakota, with a registered office in South Dakota. DM operates as a subsidiary of DS, which is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

11. DSP, DS, and DM design, manufacture, test, package, label, distribute, sell and/or offer for sale certain total knee replacement prostheses, including the SIGMA Device.

12. Defendant DePuy, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. At all relevant times, DePuy, Inc. conducted regular and sustained business in South Dakota by selling and distributing its products in South Dakota.

13. As DOI's parent company, DePuy, Inc. is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the SIGMA Device, as well as monitoring and reporting adverse events associated with SIGMA. Upon information and belief, DePuy, Inc. participated in reviewing, investigating and/or responding to FDA adverse events and/or MAUDE reports related to the SIGMA Device, and in the decision of whether to submit reports of SIGMA failures to the FDA.

14. Defendant DePuy International, Ltd. ("DIL") is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom, and at all times relevant was doing business within the United States. At all relevant times, DePuy, International, Ltd. conducted regular and sustained business in South Dakota by selling and distributing its products in South Dakota.

15. DIL makes, designs, imports, distributes, labels, sells and/or offers for sale certain total knee replacement prostheses, including the SIGMA Device.

16. DePuy Ireland Unlimited Company ("DePuy Ireland") is a company and a citizen of Ireland with its principal place of business located at Loughbeg Industrial Estate, Loughbeg Ringaskiddy, County Cork, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Ireland Unlimited Company conducted regular and sustained business in South Dakota by selling and distributing its products in South Dakota.

17. At all times relevant, DePuy Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the SIGMA Device, as well as monitoring and reporting adverse events associated with SIGMA. DePuy Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and MAUDE reports concerning SIGMA Device failures.

18. DePuy Synthes Johnson & Johnson Ireland Ltd. ("Synthes Ireland") is an entity doing business and organized in Ireland with its principal place of business located at Unit 2, Block 10, Blanchardstown Corporate Park, Dublin 15, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Synthes Johnson & Johnson Ireland Ltd. conducted regular and sustained business in South Dakota by selling and distributing its products in South Dakota.

19. At all times relevant, Synthes Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products,

including the SIGMA Device, as well as monitoring and reporting adverse events associated with SIGMA.

20. Synthes Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and/or MAUDE reports concerning SIGMA Device failures.Defendants DSS, DOI, DIL, DSP, DS, DM, DePuy, Inc., Device Business Services, DePuy Ireland and Synthes Ireland are collectively referred to as "DePuy" and the "DePuy Synthes Companies." The DePuy Synthes Companies are part of the Johnson & Johnson Family of Companies. The DePuy Synthes Companies are a group of functionally-integrated companies with shared management, administrative and general functions, including human resources, legal, quality control, customer service, sales administration, logistics, information technology, compliance, regulatory, finance and accounting and are considered a single business enterprise.

21. Defendant Johnson & Johnson International is and, at all times relevant, was a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and regularly conducted business in the State of South Dakota by selling and distributing its products in South Dakota.

22. As one of DePuy's parent companies, Johnson & Johnson International is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the SIGMA Device, as well as monitoring and reporting adverse events associated with SIGMA.

Johnson & Johnson International participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports concerning the SIGMA Device.

23. Plaintiff have suffered personal injuries as a direct and proximate result of DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction; Medical Device Business Services, Inc.; DePuy Orthopaedics, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes, Inc.; DePuy Mitek, Inc.; DePuy, Inc.; DePuy International, Ltd.; DePuy Ireland Unlimited Company; DePuy Synthes Johnson & Johnson Ireland Ltd.; Johnson & Johnson International; Johnson & Johnson; and Johnson & Johnson Services Inc. (collectively "Defendants") conduct and misconduct, as described herein, in connection with the design, development, manufacturing, testing, packaging, advertising, marketing, distributing, labeling, warning and sale of the Sigma Device.

24. Defendant Johnson & Johnson is the parent company of Defendants DePuy International Limited, DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd.

25. Defendant Johnson & Johnson is the alter ego of wholly owned subsidiaries Defendants, DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd ("subsidiary Defendants"). Defendant Johnson & Johnson has used these named subsidiary Defendants as its agents; and/or Defendant Johnson & Johnson and the named subsidiary Defendants are one single integrated enterprise.

JURISDICTION AND VENUE

31. This court has subject matter jurisdiction pursuant to 28 United States Code § 1332 as to the claims of the Plaintiff.

32. The amount in controversy alleged by each of the respective individual Plaintiff will exceed seventy-five thousand dollars ($75,000.00).

COMMON ALLEGATIONS APPLICABLE TO ALL COUNTS

PLAINTIFF SPECIFIC BACKGROUND

33. On or around November 2010, the Plaintiff underwent a total knee arthroplasty to her left knee at Sanford USD Medical Center in Sioux Falls, South Dakota.

34. Upon information and belief, plaintiff was implanted a DePuy Sigma Total Knee System.

35. Plaintiff continued to suffer pain upon movement to her left knee through its use.

36. On November 2019, the Plaintiff underwent revision surgery of all components of the left total knee arthroplasty at Black Hills Surgical Hospital in Rapid City, South Dakota. The surgeon found that upon entering the knee joint there was evidence of significant metallosis with black tarry material consistent with titanium erosion. All components were explanted.

PMA CLAIMS

I. DEPUY AND JOHNSON & JOHNSON FAILED TO COMPLY WITH THE TERMS OF THEIR PMA

37. Manufacturers of Class III devices such as the DEPUY SIGMA P.F.C. KNEE are required to obtain premarket approval ("PMA") from the Food and Drug Administration before they can make their products available to patients. 21 U.S.C. § 360(e). The PMA process is part of the regulatory framework of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1976.

38. The duties of a Class III medical device manufacturer do not end with PMA approval. Instead, the MDA imposes a number of ongoing requirements, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order pursuant to 21 C.F.R. §

814.80, and to conduct ongoing safety studies and notify the FDA of any unexpected serious problems with the device.

39. A U.S. manufacturer of Class III medical devices with PMA approval must comply with the FDA's Quality Systems Regulations ("QSR"). 21 CFR § 820 *et seq*. The specific QSR promulgated by the FDA are known as Current Good Manufacturing Practices ("CGMP"). 21 CFR § 820.1(a). A manufacturer must satisfy these quality standards in the manufacture and production of medical devices. 21 CFR § 820.1(a).

40. The purpose of the CGMP requirements is to govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. 21 C.F.R. § 820.1(a)(1). To comply with CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. §§ 820.1–.250).

41. These quality standards include the duty to identify and respond to a "nonconforming product." A manufacturer, such as Depuy , must "establish and maintain procedures to control product that does not conform to specified requirements," such as a failure to conform to performance and design standards set forth in the manufacturer's PMAs and supplements. 21 CFR § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSR also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the

product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21 CFR § 820.100.

42. FDA's CGMP/QSR may require a manufacturer to test for, monitor for (through post-marketing surveillance), discover, investigate and remedy issues related to the safe and effective use of a medical device as approved. A part of satisfying these post-marketing surveillance duties can be to formulate and then effectively execute a Postmarketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 CFR § 822.8.

43. Similar to Postmarketing Surveillance Plans, CGMP/QSR require a manufacturer to review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 CFR § 820.198(b).

44. An investigation must be completed when a complaint involves the possible failure of a device, its labeling or its packaging to meet any of its specifications, unless an investigation for a similar complaint has already been performed. 21 CFR § 820.198(c)

45. Also similar to Postmarketing Surveillance Plans, a device manufacturer is required to establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 CFR § 820.250 and 21 CFR § 820.1(a)(3).

46. A medical device manufacturer is required to comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device.

47. In particular, a manufacturer must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21 U.S.C. § 360i. "Serious injury" is defined to mean an injury that "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure…." *Id.*

48. According to its Congressional mandate, the FDA must establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360i.

49. Adverse events associated with a medical device must be reported to the FDA within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction was to recur. 21 CFR § 803.50(a).

50. This reporting is mandatory and is a condition of continued PMA approval. 21 CFR § 814.82. Such reports must contain all information reasonably known to a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 CFR § 803.50(b)(1).

51. In addition, a manufacturer is responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. 21 CFR § 803.50(b)(3). A manufacturer must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 CFR § 803.52(f), (9).

52. A manufacturer must report to the FDA in five (5) business days after becoming aware of any Medical Device Report ("MDR") event or events, including a trend analysis, which necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. 21 CFR § 803.53.

53. This reporting is mandatory and a condition for continued PMA approval. A device manufacturer must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. 21 CFR § 806.10(a). FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by a manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 CFR § 806.10(b).

54. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. A manufacturer must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. 21 CFR § 806.10(c).

55. FDA regulations state: "Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 CFR § 7.3(g).

56. A Recall does not necessarily mean a removal of a marketed device, but may also include its "correction" by "repair, modification, adjustment, relabeling, destruction, or

inspection (including patient monitoring) of a product without its physical removal to some other location." 21 CFR § 7.3(h).

57. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with the federal requirements. 21 U.S.C. § 351(e) & (h).

58. Devices subject to an FDA recall are, by definition, adulterated and prohibited for introduction into interstate commerce by the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 331(a).

II. DEPUY IS SUBJECT TO COMMON LAW DUTIES UNDER NUMEROUS LONG-STANDING STATE LAW PRINCIPLES

A. Depuy Voluntarily Assumed Various State Law Duties

59. Under longstanding common law in each state where Plaintiffs reside, a defendant can voluntarily assume or affirmatively undertake a duty of care through their representations, statements, words, and actions.

60. By agreeing to only sell the DEPUY SIGMA P.F.C. KNEE under the conditions listed in the PMA, by making affirmative representations about surgeon skill on its website, by communicating to the medical community and Plaintiffs outside the label about the safety of the device, and by and through its other affirmative actions as described above, Depuy assumed a duty of reasonable care to carry out its obligations of the PMA and to update the medical community and Plaintiffs about the safety of its device.

61. A manufacturer can affirmatively undertake a duty to properly train, instruct, or assist a physician on the surgical implantation of its device, and Depuy did so here.

62. First, Depuy assumed the FDCA duty to be truthful to the FDA and to others about the safety of the DEPUY SIGMA P.F.C. KNEE through voluntary conduct under state law. In an attempt to increase sales and convince the surgeons, medical community, patients, public, and FDA that its metal-on-metal DEPUY SIGMA P.F.C. KNEE devices were safe, Depuy voluntarily undertook a duty to provide truthful, current information about the safety of the DEPUY SIGMA P.F.C. KNEE devices each time it made its false and misleading representations.

63. Depuy then failed to exercise reasonable care to perform its undertaking to provide the surgeons, medical community, patients, public, and FDA with current, truthful information about the safety of the DEPUY SIGMA P.F.C. KNEE .

64. Depuy should have recognized, and in fact did recognize, at the time those representations were made, that providing truthful, current information about the safety of the DEPUY SIGMA P.F.C. KNEE was necessary to protect patients from increased risks of harm, including serious injury.

65. Depuy should have recognized, and in fact did recognize, at the time those representations were made, that providing truthful, current information about the safety of the DEPUY SIGMA P.F.C. KNEE devices would cause the surgeons, medical community, patients, public, and FDA to rely on those representations for the DEPUY SIGMA P.F.C. KNEE use—which they did.

66. Moreover, once Depuy made those false and misleading representations, an additional duty to correct and clarify the misrepresentations with current and accurate information concerning the safety of the DEPUY SIGMA P.F.C. KNEE was imposed on Depuy because, without correcting and clarifying its misrepresentations, Depuy would and did create an unreasonable risk of serious harm to patients, including Plaintiffs.

67. Depuy failure to exercise reasonable care to perform its undertaking to provide the surgeons, medical community, patients, public, and FDA with current, truthful information about the safety of the DEPUY SIGMA P.F.C. KNEE , and its subsequent failure to correct and clarify those misrepresentations, foreseeably caused Plaintiffs the physical harm of which they complain in this amended complaint.

68. Depuy assumed various state law duties by voluntarily agreeing—and in fact, demanding—to train physicians to implant the Depuy Sigma P.F.C. Knee product using its exact methods.

69. As required by 21 C.F.R. § 803.3, Depuy also agreed to voluntarily provide to the FDA an analysis of adverse events and complaints related to the DEPUY SIGMA P.F.C. KNEE system. But Defendant failed to satisfy that requirement.

70. By agreeing to only sell the DEPUY SIGMA P.F.C. KNEE under the conditions listed in the PMA, by making affirmative representations about surgeon skill on its website, and through its other affirmative actions as described above, Depuy assumed a duty of reasonable care to carry out its obligations of the PMA.

71. As discussed above and incorporated herein, Depuy made numerous misrepresentations to the medical community, the general public, and potential patients, touting the safety of Depuy DEPUY SIGMA P.F.C. KNEE device.

72. By providing information to the medical community and directly to patients about the safety of the DEPUY SIGMA P.F.C. KNEE from third parties like the British health authorities or independent studies, outside of the FDA-approved labeling, Depuy voluntarily assumed a duty to use reasonable care to update the medical community and patients, including Plaintiffs, about new information about the safety of the DEPUY SIGMA P.F.C. KNEE . Depuy violated its duties by not updating the medical community and patients, including Plaintiffs, about

new information about the safety of the DEPUY SIGMA P.F.C. KNEE from the same sources Depuy had previously cited as proof of the Sigma P.F.C. Knee's safety. These violations caused Plaintiffs' injuries.

73. Depuy violated its voluntarily assumed duties by not appropriately training surgeons or sending adverse event reports to the FDA.

74. According to federal duties imposed by the PMA, Depuy had the on- going duty to provide the FDA with adverse event and defective device reports regarding the DEPUY SIGMA P.F.C. KNEE . In a majority of states, there is a parallel state duty to monitor the sale and use of the DEPUY SIGMA P.F.C. KNEE , to discover defects associated with the DEPUY SIGMA P.F.C. KNEE , and to warn the medical community, consumers, and Plaintiff of any dangers associated with the device.

B. <u>The DEPUY SIGMA P.F.C. KNEE Was Misbranded Under FDCA And Parallel State Statutes</u>

75. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 352(a) & (j).

76. The "labeling" of a device pursuant to the FDCA and FDA regulations includes not only labeling specifically approved by the FDA but also includes all written, published or other material which the manufacturer publishes or distributes relating to the device in addition to materials specifically approved by the FDA. Such material may include advertising or promotional material distributed in relation with the device.

77. A "misbranded" device is prohibited for introduction into interstate commerce by the FDCA. 21 U.S.C. § 331(a).

78. The DEPUY SIGMA P.F.C. KNEE System provided a "Patient Information" document to patients receiving DEPUY SIGMA P.F.C. KNEE implants. These documents constitute "labeling" under 21 U.S.C. § 321(m).

79. The "Patient Information" document failed to reference the risk of tibial loosening in its "Potential Risks" section for years, even though DEPUY knew or should have known of the risk of metallosis based on the studies it submitted or referenced as part of its PMA application and documents it provided to implanting physicians.

80. Although Depuy was in the best position to make changes to its device labeling, it only updated the Patient Information section after being told to do so by the FDA. Depuy made this misleading omission even though the company knew about the risks of tibal loosening for years prior to putting this product on the market.

81. DEPUY therefore had information that it knew or should have known made information in the labeling false or misleading.

82. Because such information in the labeling was false or misleading, the device was misbranded under 21 U.S.C. §§ 321(n) and 352(a).

83. Under 21 U.S.C. § 352(t), the device was also misbranded per se because Depuy failed to furnish material and information required by 21 U.S.C. § 360i.

84. Under 21 U.S.C. § 352(t), the device was also misbranded per se because Depuy was ordered at the time of the device's approval to conduct a post-market approval study under 21 U.S.C. § 360*l*, which order Depuy failed to comply with.

85. Depuy had information that it knew or should have known made information in the label false or misleading.

86. Because such information in the label was false or misleading, the device was misbranded under 21 U.S.C. § 352(a) and 21 U.S.C. § 331(q)(2).

87. Under 21 U.S.C. § 352(t), the device was misbranded per se because Depuy failed to furnish material and information required by 21 U.S.C. § 360i.

88. Under 21 U.S.C. § 352(t), the device was misbranded per se because Depuy was ordered at the time of the device's approval to conduct a post market approval study under 21 U.S.C. § 360l, with which Depuy failed to comply.

C. Depuy Fraudulently Concealed Plaintiffs' Claims

89. Depuy fraudulently concealed the fact that it did not actually have the legal protection provided of preemption under the PMA. Depuy failed to disclose information to the scientific and medical communities, as well as consumers, in violation of its duty to disclose. The information purposely withheld was material, and was information that consumers, such as Plaintiff could not have learned without Depuy disclosure.

90. Specifically, Depuy intentionally withheld from consumers the fact that it no longer enjoyed PMA protection; at a minimum, this material fact was intentionally withheld from the public, and consumers such as Plaintiff, until the formal recall in September 2015, and even thereafter, as Depuy continued to assert that it enjoyed preemption protection from all claims. Accordingly, consumers, such as Plaintiff, were misled into believing that they had no claim for the injuries suffered due to the DEPUY SIGMA P.F.C. KNEE system.

91. Because Depuy intentionally withheld this material information concerning the PMA status, numerous Plaintiffs were harmed by relying on the nondisclosure, and acted on such reliance.

92. Because Depuy continues to maintain that it has PMA protection from all claims, and because of the fraudulent concealment of material facts, Plaintiff is well-within the statute of limitations at the time of this filing. Plaintiffs' statute of limitation would have begun to run from the recall date in September 2015, or the date of his revision surgery, whichever is later.

93. Defendant fraudulently concealed from and/or failed to disclose to Plaintiffs, Plaintiffs' healthcare providers, and the medical community that its Depuy Sigma P.F.C. Knee products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

94. The facts concealed and/or not disclosed to Plaintiff and the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize Defendant's Depuy Sigma P.F.C. Knee products.

95. Defendant's fraudulent concealment, as complained of herein, constitutes a parallel violation of common law of all states where Plaintiffs reside that predates and operates independently from the above federal requirements.

D. Depuy State Law Duties Are Defined by Federal Regulations, The PMA, And Other FDA Actions

96. Depuy is subject to a duty of reasonable care under the common law in each state in which Plaintiffs reside, and this common law duty can be set, defined by or otherwise informed by federal statutes, regulations and other FDA actions. To the extent these duties are parallel with Depuy requirements under federal law, Plaintiffs' claims arising from violations of these duties are not preempted by federal law.

97. Specifically, Depuy's conduct violated the FDCA and gave rise to recovery under state law, even in the absence of the FDCA, because, as relevant to this section, Plaintiffs' state law duties are defined by the FDCA and its attendant regulations and approval order; and because Depuy made voluntary statements outside the label about the safety of the DEPUY SIGMA P.F.C. KNEE .

98. As detailed above, Depuy made statements and representations outside the FDA-approved labeling to surgeons and the medical community about the safety of the DEPUY

SIGMA P.F.C. KNEE that were false and materially misleading, including that the DEPUY SIGMA P.F.C. KNEE : was safer than it was, safer than other metal-on-metal devices, safer than ceramic knee devices, had lower failure rates; and Depuy omitted material facts from sources that were later updated to cast doubt on the safety of the DEPUY SIGMA P.F.C. KNEE

99. Depuy was also required by the FDCA and its corresponding regulations and approval order, detailed supra Section IV, to comply with post-approval obligations, such as: updating the FDA with current failure rates, complying with specific reporting, investigative, and performance-related duties; and properly training surgeons using the DEPUY SIGMA P.F.C. KNEE devices.

100. Depuy's FDCA-imposed duties arose out state law contract principles. Depuy's duty to provide current, truthful information to the FDA and others about the safety of the DEPUY SIGMA P.F.C. KNEE arose out of the performance of a contract where Depuy expressly and impliedly agreed that it would provide the safety-related information to the FDA and others in a truthful, current manner (and satisfy the attendant FDCA requirements), during the PMA approval process, and through timely supplementation following the approval process (as stated in the Approval Order)—in exchange for the right to sell the DEPUY SIGMA P.F.C. KNEE within the United States.

101. Depuy received and accepted the benefit without materially satisfying its bargained-for performance obligations.

102. Depuy's duty to provide current, truthful information to the medical community and public about the DEPUY SIGMA P.F.C. KNEE also arose out of contract principles where Depuy expressly and impliedly agreed with the FDA that any voluntary representations made to the public (or others outside the FDA) about the DEPUY SIGMA P.F.C. KNEE would be

truthful and otherwise in compliance with the Approval Order—in exchange for the right to sell the DEPUY SIGMA P.F.C. KNEE within the United States.

103. Depuy received and accepted the benefit without materially satisfying its bargained-for performance obligations.

104. Depuy's FDCA-imposed duties to be truthful about the safety of the DEPUY SIGMA P.F.C. KNEE arose out of its special relationships with the surgeons, medical community, patients, public, and FDA. Depuy performed important services to medical professionals and, indirectly to patients, by manufacturing, marketing, and selling the DEPUY SIGMA P.F.C. KNEE products that would be implanted in patients' bodies, and if performed improperly and based on false and misleading information, would have catastrophic consequences.

105. Depuy had a duty to disclose this information to the medical professionals who would then select and implement the best medical treatment plan for Plaintiffs' knee-related conditions.

106. Depuy was in a unique position of trust and confidence by not only manufacturing, marketing, and selling the DEPUY SIGMA P.F.C. KNEE , but also by funding and conducting its own studies on which it relied to demonstrate the safety of DEPUY SIGMA P.F.C. KNEE , and then failing to disclose its relationship to those studies—and citing specific literature and research later shown to be false and misleading.

107. Depuy's relationship with them was of a nature where it would be expected that the FDA, medical providers, and patients in need of knee replacement would rely on the representations Depuy made about the safety of the DEPUY SIGMA P.F.C. KNEE , and later lack of clarification would reasonably be taken as an appearance of safety.

108. The surgeons, medical professionals, patients, and FDA detrimentally and justifiably relied on Depuy's safety-related representations, which caused Plaintiffs their serious injuries, as described in this amended complaint.

109. Depuy had a duty to correct these misrepresentations and dangers caused by DEPUY SIGMA P.F.C. KNEE , because it should have known, and in fact did know, the information served a serious purpose; the surgeons, medical community, patients, public, and FDA intended to rely and act on it; the information was materially false or misleading; and the information would cause Plaintiffs serious injury.

110. Depuy's FDCA-imposed duties were adopted as the standard of care under Plaintiffs' state laws—a violation of which constitutes negligence *per se*. The FDCA, with its attendant federal regulations and approval order, impose specifically defined duties on Depuy with which it must comply to sell the DEPUY SIGMA P.F.C. KNEE devices in the United States, detailed supra Section IV, including: to ensure the safe and effective use of the device through specific reporting, investigative, and performance-related requirements.

111. These duties are imposed on Depuy for the purpose of protecting patients, like Plaintiffs, from the very kind of injuries of which they complain in this amended complaint.

112. By failing to comply with the federally-imposed duties through untruthful, misleading, and materially incomplete disclosures and information to the FDA during and after PMA approval, and to the surgeons, medical community and public by voluntary disclosure about the safety of the DEPUY SIGMA P.F.C. KNEE , Depuy has proximately caused Plaintiffs' injuries.

113. Depuy had actual or constructive knowledge that Plaintiffs and other patients in Plaintiffs' position would rely upon said misrepresentations and/or suppressions when

making decisions about surgery that involved the DEPUY SIGMA P.F.C. KNEE , and Plaintiffs and other patients did in fact rely upon these misrepresentations and/or suppressions as described above.

114. Each of these FDCA violations constitute a *per se* violation of negligence under Plaintiffs' state law claims.

115. Thus, Depuy could change its labeling without FDA approval, and had an affirmative duty to use the Special PMA Supplement label change process to change its labeling when information about new safety risks arose.

116. Depuy violated its duty to update its labeling through the Special PMA Supplement process after July 30, 2010, and that violation caused Plaintiffs injuries.

E. Depuy Had A Continuing, Post-Sale Duty to Warn the Medical Community of Dangers Associated With the DEPUY SIGMA P.F.C. KNEE

117. According to duties imposed by the PMA, Depuy had the on-going duty to provide the FDA with adverse event and defective device reports regarding the DEPUY SIGMA P.F.C. KNEE . In the majority of states where Plaintiffs reside, there is a parallel state duty to monitor the sale and use of the DEPUY SIGMA P.F.C. KNEE , to discover defects associated with the DEPUY SIGMA P.F.C. KNEE , and to warn the medical community, consumers, and Plaintiff of any dangers associated with the device after the original implantation of the device. As discussed above and incorporated herein, Depuy made numerous representations to the medical community, the general public, and potential patients, touting the safety of Depuy's DEPUY SIGMA P.F.C. KNEE device over the course of several years.

118. Depuy left the impression with surgeons and the medical community that the failure rate of the DEPUY SIGMA P.F.C. KNEE was lower than it really was - and that the

DEPUY SIGMA P.F.C. KNEE was safe - by failing to provide updated studies and survivorship, including Depuy's own PMA- mandated studies.

119. Specifically, Depuy had actual and constructive knowledge of the risks associated with the DEPUY SIGMA P.F.C. KNEE device, and failed to post-sale warn the medical community, consumers, and Plaintiff in particular:

a. Depuy was obligated and failed to take reasonable efforts to issue a post- sale warning to the medical community, consumers, and the Plaintiff of the defective and unreasonably dangerous condition associated with the DEPUY SIGMA P.F.C. KNEE device that was available either at the time of distribution or in sufficient time before Plaintiffs' injury so that an effective and reasonable supplemental warning could have been given; and/or

b. Depuy was obligated and failed to take reasonable efforts to warn the medical community, consumers, and Plaintiff of the defective and unreasonably dangerous condition associated with the device that was unknown at the time of sale but which was subsequently discovered after the sale of the device; and/or

c. Depuy failed to take reasonable efforts to issue a post-sale warning after learning of the Sigma P.F.C. Knee's high failure rates and risks associated with metal ions when a reasonable person in Depuy's position would have provided such a warning to the medical community, consumers, and the Plaintiff in particular; and/or

d. Depuy had the obligation to and failed to take reasonable efforts to issue a post-sale warning when it knew or should have known of significant hazards associated with misuse or alteration of the DEPUY SIGMA P.F.C. KNEE device. The foreseeable use of the DEPUY SIGMA P.F.C. KNEE device was unreasonably unsafe and Depuy was required to warn the medical community, consumers, and the Plaintiff; and/or

e. Depuy had the obligation and failed to take reasonable efforts to issue a post-sale warning after the initial sale of the DEPUY SIGMA P.F.C. KNEE device because it commenced and/or had knowledge of safety-related research sufficient to induce the medical community, consumers, and the Plaintiff to reasonably expect Depuy to disseminate hazard information.

120. Depuy's failure to carry out its duty to post-sale warn caused Plaintiffs' injuries.

121. Depuy's failure to carry out its duty to post-sale warn was a proximate cause of Plaintiffs' injuries; and/or

122. Depuy's failure to carry out its duty to post-sale warn was a direct cause of Plaintiffs' injuries; and/or

123. Depuy's failure to carry out its duty to post-sale warn was a substantial factor resulting in Plaintiffs' injuries.

COUNT I
PRODUCT LIABILITY
PURSUANT TO N.J.S.A. 2A:58C-1 to -11, *et seq.*

124. At all relevant times hereto, the Depuy Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Depuy Sigma Knee.

125. Defendant designed and/or manufactured the DEPUY SIGMA P.F.C. KNEE Systems implanted in Plaintiffs' bodies, in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to it, as well as the duties created by virtue of the agreements in the Approval Order.

126. At the time the DEPUY SIGMA P.F.C. KNEE Systems, including the femoral and tibial components left the control of Defendant, Depuy , they were unreasonably dangerous due to Defendant's non-compliance with the Act, and the regulations promulgated pursuant to it and the Approval Order in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the DEPUY SIGMA P.F.C. KNEE, in violation of 21 C.F.R. § 820.30(f);

b. Failed to validate the anticipated loosening/wear of the tibial plate prior to its release into commercial distribution, in violation of 21 C.F.R. § 820.30(g). For example, as recently as 2012, Depuy admitted to the FDA that *in vitro* wear data

from machine simulators had little clinical relevance to the performance of the DEPUY SIGMA P.F.C. KNEE implant *in vivo*;

c. Failed to establish and maintain appropriate reliability assurance testing to validate the DEPUY SIGMA P.F.C. KNEE design both before and after its entry into the marketplace, in violation of 21 C.F.R. § 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the Sigma Knee's latent propensity to effuse metallic contaminants into the human blood and tissue. Instead of conducting adequate studies, Depuy attempted to blame bio-compatibility studies on, among other things, patients who wear costume jewelry;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. § 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. § 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the DEPUY SIGMA P.F.C. KNEE , returned DEPUY SIGMA P.F.C. KNEE , and other quality problems associated with the DEPUY SIGMA P.F.C. KNEE , in violation of 21 C.F.R. § 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the tibial plate was Malfunctioning [as defined in 21 C.F.R. § 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. § 820.198. For example, instead of adequately investigating these incidents, Depuy in its PMA annual reports to the FDA blamed catastrophic product failures of the DEPUY SIGMA P.F.C. KNEE on generalized issues such as "pain" or "squeaking" or "allergic reaction";

i. Failed to conduct complete device investigations on returned DEPUY SIGMA P.F.C. KNEE and components, including the acetabular component, in violation of 21 C.F.R. § 820.198;

j. Continued to place the DEPUY SIGMA P.F.C. KNEEinto the stream of interstate commerce when it knew, or should have known, that the tibial plate was Malfunctioning [as defined in 21 C.F.R. § 803.3] or otherwise not responding to its Design Objective Intent; and/or,

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training.

127. Depuy failure to comply with the above-stated requirements is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Depuy allowed and encouraged its commission-based salesmen to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems;

b. Depuy willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Depuy received hundreds of adverse reports regarding the DEPUY SIGMA P.F.C. KNEE system but delayed its reporting to the FDA;

d. Depuy failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Depuy also failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Depuy failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Depuy failed to investigate all Device Failures;

h. Depuy failed to revise its instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the DEPUY SIGMA P.F.C. KNEE ;

i. Depuy also knew but failed to disclose that some of the surgeons — both overseas and domestically — upon whose data it relied to boast a high success rate for the DEPUY SIGMA P.F.C. KNEE had been paid financial remuneration in order to use and promote the DEPUY SIGMA P.F.C. KNEE ;

j. Depuy , as a result of increased demand for the product, failed to properly train all surgeons and Original Core Surgeons using the product as required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

k. Depuy also misrepresented to the surgeons in the United States that *in vivo* testing of the DEPUY SIGMA P.F.C. KNEE had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable;

l. Depuy represented to medical professionals and Plaintiffs that the DEPUY SIGMA P.F.C. KNEE was safer than other metal-on-metal devices, had a low revision/failure rate, and was safe for use by communicating statistics and actions from health authorities, but failing to update the medical community and Plaintiffs when additional information became available and as new risks arose, leaving a false impression in the minds of the medical community and plaintiffs about the safety of the DEPUY SIGMA P.F.C. KNEE ;

m. Depuy failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the DEPUY SIGMA P.F.C. KNEE system, thereby misrepresenting the efficacy and safety of the Depuy Sigma P.F.C. Knee products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the DEPUY SIGMA P.F.C. KNEE system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

128. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a DEPUY SIGMA P.F.C. KNEE System that was implanted in Plaintiffs' body, and failed and such failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained and endured as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiff, endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to,

physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

129. This cause of action is based entirely on the contention that Depuy actions that violated the state statutes and common laws listed below also violated parallel federal safety statutes and regulations, as well as the conditions established in the PMA Approval Order with which Defendant agreed to comply to obtain premarket approval of the device.

130. The Depuy Defendants designed, manufactured, marketed, and sold the Depuy Sigma Knee to medical professionals and their patients, knowing they would be implanted for knee replacements.

131. The Depuy Sigma Knee was designed, manufactured, marketed and sold by Defendants, reached Plaintiff without substantial change in its condition and was used by Plaintiff and Plaintiff's physicians in a reasonably foreseeable and intended manner.

132. The Depuy Sigma Knee was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

133. At no time did Plaintiff have reason to believe that Depuy Sigma Knee was in a condition not suitable for their proper and intended use among patients.

134. The Depuy Sigma Knee was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

135. The Depuy Sigma Knee was defective, due to defective design rendering the system unsafe.

136. The Depuy Sigma Knee was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than its foreseeable

therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

137. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of the Depuy Sigma Knee. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Depuy Sigma Knee in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

138. The Depuy Sigma Knee is defective in design because of its propensity to loosen, specifically, metal tibial plate was more likely to loosen, and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

139. The Depuy Sigma Knee is defective in design because of the increased risk for radiolucent lines, loosening and ultimately device failure stemming from the porous coated, uncemented trabecular metal tibial plate. The Sigma is also defective in design because the risk of revision surgery is unreasonably greater than other knee implants. The Depuy Sigma Knee offers no clinical benefit over the traditional knee replacement device or devices that feature the standard tibial plate/tibial component that involves cementing or an appropriate stability attachment to the tibia bone.

140. The design of the Sigma Knee was flawed in that while it was theoretically designed to remain in place once implanted in the patient, but in practice, its design would actually cause the tibial plate to loosen and or dislodge, causing injury.

141. The Sigma Knee was designed in a manner presenting:

i. An unreasonable risk of loosening due to the design allowing the tibial plate to be used without cementing the plate to the tibia bone;

ii. An unreasonable risk of flawed sealing with the tibial insert of the rotating platform knee system, which evidence poor placement and are an early warning sign of loosening and failure;

iii. Insufficient structural integrity and design to withstand normal, foreseeable placement within the human body;

142. The Depuy Sigma Knee is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, inter alia, the propensity of the Sigma's porous coated, uncemented trabecular metal tibial plate to loosen and cause serious pain and necessitate additional surgery; the postmarketing experience of higher rates of loosening and revision surgery with the Depuy Sigma Knee; and the probability of suffering loosening, pain and revision surgery.

143. The Depuy Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, or provide a safer tibial plate with cementing to the Sigma device, even though such products were feasible and marketable at the time Defendants sold Depuy Sigma Knee to Plaintiff.

144. The Depuy Sigma Knee is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, inter alia, the increased risk of failure of Depuy Sigma Knee resulting in revision surgery which is unreasonably greater than other knee implants and safer tibial plate components.

145. Defendants had knowledge and information confirming the defective and dangerous nature of the Depuy Sigma Knee.

146. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and their physicians that Depuy Sigma Knee causes serious permanent

injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

147. Further, Depuy designed, manufactured, inspected, labeled, leased, distributed, marketed, sold, and otherwise released the Depuy Sigma P.F.C. Knee product the into the stream of commerce.

148. In doing so, Defendant directly advertised or marketed the DEPUY SIGMA P.F.C. KNEE product to the FDA, health care professionals, and consumers or persons responsible for consumer.

149. Defendant thus had a duty to warn of the risks associated with the device.

150. Defendant failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, about the true risks of the Depuy Sigma P.F.C. Kneeproduct, including that the device would:

a. Fail at a much higher rate than suggested;

b. Cause tibal loosening, despite being aware of the risk of tibal loosening as early as 2006;

151. Moreover, Defendant failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, about the true risks of the Depuy Sigma P.F.C. Knee product, by:

a. Failing to adequately train physicians on the requisite technique required to implant the DEPUY SIGMA P.F.C. KNEE device, a duty voluntarily assumed by Depuy . Depuy own warning label advises that only physicians with the proper training should implant the DEPUY SIGMA P.F.C. KNEE product; Defendant

also indicates that physicians should "contact Depuy for the DEPUY SIGMA P.F.C. KNEE surgical technique manual and procedural training protocol."

b. Failing to adequately report post-market adverse events to the FDA when known, as required by 21 C.F.R. § 803.50(a);

c. Failing to report new clinical investigations and studies that concern the DEPUY SIGMA P.F.C. KNEE product as required by 21 C.F.R. 814.84(b)(2);

d. Failing to use the Changes Being Effected process to update medical professionals in compliance with FDA directives.

152. Upon obtaining knowledge of these potential device failure modes, the Defendant was required under the DEPUY SIGMA P.F.C. KNEE PMA, 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq. and the FDA Recognized Consensus Standard ISO 14971 to use this information to routinely update the risk analyses for the DEPUY SIGMA P.F.C. KNEE device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendant was required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

153. As to manufacturing, Depuy manufactured, distributed, and/or sold the SIGMA P.F.C. KNEE System, including the femoral and tibial plates , that were implanted in Plaintiffs' knee joints and failed.

154. At the time Depuy manufactured, distributed, and/or sold the SIGMA P.F.C. KNEE System that was implanted in Plaintiffs' knee joints, it was required to comply with the FDA's Quality Systems Regulations ("QSR"), 21 C.F.R. § 820 *et seq*. Depuy 's failure to follow

these regulations was a cause of the manufacturing defect in the SIGMA P.F.C. KNEE System implanted in Plaintiffs' body.

155. Depuy violated the CGMP requirements when it failed to do the following:

a. Govern the manufacturing methods used to manufacture, produce and distribute the SIGMA P.F.C. KNEE;

b. Failed to govern the manufacturing facilities and the quality controls used for the design, manufacture, packaging, labeling, storage, installation and servicing of all finished SIGMA P.F.C. KNEE systems;

c. Failed to adopt procedures and controls relating to design control; quality assurance; manufacturing and processing; process validation; device inspection and corrective and preventive action.

d. Failed to ensure that the initial specifications for hardness, radial clearance, sphericity, wall thickness and surface roughness were followed during the manufacturing process.

156. Depuy further violated FDA-required manufacturing specifications when it failed to manufacture the SIGMA P.F.C. KNEE system Plaintiffs received in a way that was consistent with the FDA premarket approval specifications, as required by 21 C.F.R. § 814.80.

157. As a further direct and proximate result of Smith & Nephew's above cited violations, the SIGMA P.F.C. KNEE system implanted in Plaintiffs was manufactured with material that did not meet the FDA's requirements for hardness, durability, surface roughness, composition, and finish.

158. The duty of a manufacturer to use due care in manufacturing a medical device predates the Medical Device Amendments, and is a duty that Depuy owes to Plaintiffs. This theory of manufacturing defect is therefore not impliedly preempted by federal law, nor is it expressly preempted as the duty is one of state tort law which is parallel to the federal requirement that the SIGMA P.F.C. KNEE System be manufactured according to the approved specifications for the medical device.

159. In addition to the above requirements, the FDA's Quality Systems Regulations ("QSR") (21 CFR § 820 *et seq*) include the duty to identify and respond to a "nonconforming product." A manufacturer, such as Depuy , must "establish and maintain procedures to control product that does not conform to specified requirements," such as a failure to conform to performance and design standards set forth in the manufacturer's PMAs and supplements. 21 CFR § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSR also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21 CFR § 820.100.

160. FDA's CGMP/QSR may require a manufacturer to test for, monitor for (through post-marketing surveillance), discover, investigate and remedy issues related to the safe and effective use of a medical device as approved. A part of satisfying these post-marketing surveillance duties can be to formulate and then effectively execute a Postmarketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 CFR § 822.8.

161. Similar to Postmarketing Surveillance Plans, CGMP/QSR require a manufacturer to review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 CFR § 820.198(b).

162. An investigation must be completed when a complaint involves the possible failure of a device, its labeling or its packaging to meet any of its specifications, unless an investigation for a similar complaint has already been performed. 21 CFR § 820.198(c).

163. Also similar to Postmarketing Surveillance Plans, a device manufacturer is required to establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 CFR § 820.250 and 21 CFR § 820.1(a)(3).

164. A medical device manufacturer is required to comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device.

165. In particular, a manufacturer must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21 U.S.C. § 360i. "Serious injury" is defined to mean an injury that "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure…." *Id.*

166. According to its Congressional mandate, the FDA must establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360i.

167. Adverse events associated with a medical device must be reported to the FDA within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction was to recur. 21 CFR § 803.50(a).

168. This reporting is mandatory and is a condition of continued PMA approval. 21 CFR § 814.82. Such reports must contain all information reasonably known to a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 CFR § 803.50(b)(1).

169. Depuy failed to manufacture the SIGMA P.F.C. KNEE System with material that met the FDA's requirements for hardness, durability, composition, and finish, in violation of 21 C.F.R. § 814.80. This resulted in excessive edge loading and wear rates, due to manufacturing deviations in wall thickness, surface roughness, sphericity, and radial clearance as described in more detail above.

170. The SIGMA P.F.C. KNEE System implanted in Plaintiffs' bodies possessed a defect in its manufacture that existed when the device left Depuy 's possession. As a result of this defect, the device did not conform to the design specifications for the SIGMA P.F.C. KNEE System approved by the FDA.

171. These defects include, but are not limited to, the above-mentioned deviations from the maximum clearance specified by Depuy for the for the SIGMA P.F.C. KNEE, and the resulting excessive linear wear rate for the SIGMA P.F.C. KNEE.

172. On information and belief, the ideal tolerances for clearance of the as-cast SIGMA P.F.C. KNEE device components were not met due to problems with the hardness of the metal and this caused too much or too little clearance, resulting in premature failure due to metallosis as described above.

173. On information and belief, the carbide volume of the metal was not controlled during manufacturing and therefore allowed for increased wear rates which resulted in premature failure due to metallosis and related causes. On information and belief, the specific contents of the metal were not controlled between batches, which allowed differences in hardness levels of the SIGMA P.F.C. KNEE, resulting in increased risk of premature failure.

174. On information and belief, the manufacturing process employed by Defendant for their SIGMA P.F.C. KNEE product, including those implanted in Plaintiffs, resulted in surface damage to the metal of the femoral components, weakening the structural integrity of Defendant's SIGMA P.F.C. KNEE product, thus increasing the risk of scratches, dislocation, higher than expected linear wear, and "edge loading" which increases the risk of dislocation and elevated blood metal ion concentration, e.g., metallosis.

175. On information and belief, Defendant maintained design and manufacturing specifications that SIGMA P.F.C. KNEE products were required to have the appropriate carbide volume of metal content, strength, size, durability, appearance, and resistance levels, and should not be distributed if they exhibited a certain degree of surface damage. The manufacturing process was intended to catch and identify any end-product SIGMA P.F.C. KNEE products that did not meet specifications and not distribute said SIGMA P.F.C. KNEE products. But Defendant failed to identify SIGMA P.F.C. KNEE devices that were out of specification.

176. These manufacturing defects rendered the SIGMA P.F.C. KNEE device unreasonably dangerous to Plaintiffs. The defect in manufacture was a cause of injury to Plaintiffs.

177. If Depuy had followed its own manufacturing specifications for clearance, hardness, and linear and volumetric wear, the premature failure of Plaintiffs' devices would not

have occurred. The above manufacturing defects are evidence of implied negligence under the doctrine of *Res Ipsa Loquitur*.

178. As a direct and proximate result of Depuy's violation of federal statutory and regulatory standards of care, and specific state laws, as set forth below, a SIGMA P.F.C. KNEE was implanted in Plaintiffs and failed, and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs as defined in 21 C.F.R. 803.3. As a direct result, Plaintiffs endured pain and suffering and have required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; physical pain and suffering, both past and future mental anguish and emotional distress, both past and future, including, but not limited to, humiliation, embarrassment, annoyance and aggravation.

179. The Act contains an express preemption provision, 21 U.S.C. § 360(k), which in relevant part states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301, et seq.]."

180. This cause of action is based entirely on the contention that Depuy violated federal safety statutes and regulations. Plaintiffs do not bring the underlying action as an implied statutory cause of action, but rather they are pursuing parallel state law claim, pursuant to the state laws as set forth below, based upon Defendant, Depuy 's violations of the applicable federal regulations.

181. Depuy 's violations of the aforementioned federal safety statutes and regulations violate each states' product strict liability and negligence laws to the extent those laws relate to manufacturing defects.

182. Depuy was engaged in the business of selling the SIGMA P.F.C. KNEE system.

183. At the time the SIGMA P.F.C. KNEE Systems, including the Femoral and tibial plates, left the control of Defendant, they were unreasonably dangerous and not fit for foreseeable use, due to non-compliance with the Act, and/or because Depuy was negligent in not taking reasonable measures in manufacturing its product against foreseeable risk, as set forth in detail above.

184. The DEPUY SIGMA P.F.C. systems which left the control of Depuy were expected to and did reach Plaintiffs without a substantial change in condition. Specifically, the DEPUY SIGMA P.F.C. system, including the Femoral and tibial plates , were properly implanted in Plaintiffs without any alteration of the DEPUY SIGMA P.F.C. system after the system left the control of Depuy . In the alternative, any changes that were made to the DEPUY SIGMA P.F.C. System implanted in Plaintiffs were reasonably foreseeable to Defendant.

185. As a direct and proximate result of Depuy 's DEPUY SIGMA P.F.C. manufacturing defects, and as a direct and proximate result of each and every state's laws as set forth above, a DEPUY SIGMA P.F.C. system including the Femoral and tibial plates , was implanted in Plaintiffs and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs as defined in 21 C.F.R. 803.3. As a direct result, Plaintiffs endured pain and suffering and have required additional and debilitating surgeries and have incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; loss of consortium; physical pain

and suffering, both past and future mental anguish and emotional distress, both past and future, including, but not limited to, humiliation, embarrassment, annoyance and aggravation.

186. Under the NJPLA, N.J. Stat. Ann. § 2A:58C-1 through 58C-11, the DEPUY SIGMA P.F.C. KNEE reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the Sigma P.F.C. Knee's defective condition, as described above, which made the product unreasonably dangerous.

187. Defendant's conduct violated these regulations and also separately violated its duties under the follow state law, thereby jeopardizing the health of patients, including Plaintiffs.

448. Had Defendant provided timely and reasonable warnings regarding the safety and efficacy of the Depuy Sigma P.F.C. Knee product, those warnings would have been heeded and no healthcare professional, including Plaintiffs' physicians, would have used the Depuy Sigma P.F.C. Knee product and no patient or consumer, including Plaintiffs, would have allowed use of the device. Defendant's failure to provide timely and reasonable warnings, instructions, and information regarding the Depuy Sigma P.F.C. Knee product rendered the device unreasonably dangerous and defective.

188. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Depuy Sigma Knee, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II
NEGLIGENCE

189. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

190. As the designer, manufacturer, distributor and seller of the DEPUY SIGMA P.F.C. , Depuy owed duties to the Plaintiffs of reasonable care under the circumstances. Those duties are defined by federal and state regulations, statutes, custom, practice, the terms of the PMA, and Depuy 's voluntary actions and assumptions of duties, among other sources.

191. Depuy breached those duties of reasonable care to Plaintiffs by the actions detailed above, including, but not limited to, failing to warn Plaintiffs and the medical community of the true risks of the DEPUY SIGMA P.F.C. , misrepresenting the true safety of the DEPUY SIGMA P.F.C. , failing to comply with the terms of the PMA, failing to update the medical community and patients when it learned or discovered new information about the risks and safety of the DEPUY SIGMA P.F.C. , and otherwise failing to recall the DEPUY SIGMA P.F.C. before it did.

192. Depuy 's breach of its duties caused Plaintiffs' injuries. The DEPUY SIGMA P.F.C. Systems, including the femoral and tibial plates , implanted in Plaintiffs' knee were distributed and/or manufactured in violation of the Act and regulations promulgated to it.

193. Depuy consistently under-reported and withheld information about the likelihood of the DEPUY SIGMA P.F.C. to fail and cause injury and complications, and has misrepresented the efficacy and safety of the DEPUY SIGMA P.F.C. products, actively misleading the medical community, patients, the public at large, and Plaintiffs.

194. Defendant knew, and continues to know, that its disclosures to the public and Plaintiffs were and are incomplete and misleading; and that Defendant's DEPUY SIGMA P.F.C. products were and are causing numerous patients severe injuries and complications. Depuy

suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

195. As a result, Depuy actively and intentionally misled and continues to mislead the public, including the medical community, health care providers, and patients, into believing that the Defendant's DEPUY SIGMA P.F.C. products were and are safe and effective, leading to the prescription for and implantation of the DEPUY SIGMA P.F.C. products into patients such as Plaintiffs.

196. Depuy failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Defendant's DEPUY SIGMA P.F.C. products. As compared to Depuy 's DEPUY SIGMA P.F.C. products, feasible and suitable alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the knee joint and similar other conditions have existed at all times relevant.

197. Depuy 's DEPUY SIGMA P.F.C. products were at all times utilized and implanted in a manner foreseeable to Defendant. Depuy failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing Defendant's DEPUY SIGMA P.F.C. products, thereby increasing the sales of the DEPUY SIGMA P.F.C. products, and also leading to the dissemination of inadequate and misleading information to patients.

198. It was the duty of Defendant, Depuy , Inc. to comply with the Act, and the regulations promulgated pursuant to it, as well as the conditions established in the Approval Order with which Defendant agreed to comply in order to obtain premarket approval of its device. Yet, notwithstanding this duty, Defendant, Depuy , Inc. violated the Act as described in detail above.

199. Subsequently, the DEPUY SIGMA P.F.C. systems implanted in Plaintiffs' knee failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by

200. Plaintiffs, as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

201. Under New Jersey law, Depuy owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein

202. The Depuy Defendants failed to warn the Plaintiff of the information that it had in its possession, custody and control regarding the functionality and defectiveness of its product prior to the Depuy device being distributed within the State of New York and prior to the defective component's installation in the Plaintiff.

203. The Depuy Defendants breached their duty of care by:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Depuy Sigma Knee, and/or to utilize and/or implement reasonably safe designs for them;

b. Failed to require cementing for all Depuy Sigma tibial plates;

c. Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of Depuy Sigma Knee when used in a reasonably foreseeable manner;

d. Failed to conduct adequate post marketing surveillance.

e. Failing to design, formulate, manufacture and incorporate or to reformulate the Depuy Sigma Knee with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff when used in a reasonably foreseeable manner;

f. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Depuy Sigma Knee in accordance with good design practices;

g. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Depuy Sigma Knee, thus misrepresenting the safety of the product;

h. Failing to make timely and adequate corrections to the manufacture, design and formulation of Depuy Sigma Knee so as to prevent and/or minimize the problems suffered by Depuy Sigma Knee use;

i. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

j. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiff' injuries having manifested themselves;

k. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,

l. Being otherwise being careless, reckless and negligent.

204. Thus, under state's laws, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the above states Legislatures to act in order to create such a remedy.

205. These states' law treats violations of federal statutes and regulations, among other things, as evidence of common law negligence.

206. Defendant also undertook a duty under the above states' law to comply with the terms of the PMA and to truthfully communicate safety information about the DEPUY SIGMA P.F.C. .

207. In addition to the details set forth above, Depuy breached its duties under the above states' laws by:

a. manufacturing actual DEPUY SIGMA P.F.C. products that differ from the specifications set forth in the CPMA, its Supplements, the Conditions of Approval and/or other federal regulations;

b. failing to manufacture the DEPUY SIGMA P.F.C. product in compliance with FDA-approved specifications in the PMA;

c. failing to correctly monitor its products to ensure that it complied with appropriate quality control procedures and to track nonconforming products;

d. failing to conduct regular risk analysis of its DEPUY SIGMA P.F.C. product, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes and failing to exercise appropriate post-market quality controls;

e. failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two-year report schedules;

f. failing to comply with applicable federal and state regulations;

g. failing to monitor the sale and use of the DEPUY SIGMA P.F.C. System; discover defects associated with the DEPUY SIGMA P.F.C. System's use; and warn the government, doctors, and users about those defects;

h. failing to adequately train Defendant's employees who provided recommendations and advice to physicians who implanted the device;

i. failing to comply with the terms of the PMA;

j. failing to recall the DEPUY SIGMA P.F.C. before September 2015;

k. failing to provide truthful and accurate information in its voluntary statements to the medical community outside the labeling;

l. failing to update the medical community as it learned of new or additional risks;

m. failing to update the medical community with information about the real-world survival rate of the DEPUY SIGMA P.F.C. , government actions about monitoring metal ion levels, and similarity between the DEPUY SIGMA P.F.C. and other MOM devices after originally providing this information to the medical community through advertisements and Dear Doctor letters as reproduced above;

n. failing to update patients with information about the real-world survivorship rate of the DEPUY SIGMA P.F.C. , government actions about monitoring metal ion levels, and similarity between the DEPUY SIGMA P.F.C. and other MOM devices after originally providing this information through marketing materials, websites and other direct-to-consumer statements; and

o. failing to properly train and educate physicians on the use of the DEPUY SIGMA P.F.C. product, Defendant accepted a duty even to the Plaintiffs' physicians to train them to implant the DEPUY SIGMA P.F.C. device correctly, and defendant did not fulfil their duty to provide all necessary information to physicians. These claims are not expressly or impliedly preempted as Depuy voluntarily agreed to accept this duty to train physicians.

208. These simple common law negligence duties are parallel to the duties under federal law, and are not preempted by any federal law. Depuy 's breach of these duties caused Plaintiffs' injuries.

209. Defendant also made false, inaccurate and misleading statements concerning the properties and effects of the DEPUY SIGMA P.F.C. product.

210. Depuy for years made voluntary statements outside the labeling and directly to patients, including Plaintiffs, that the DEPUY SIGMA P.F.C. was safe. This message was delivered explicitly and implicitly, was designed to convey that the DEPUY SIGMA P.F.C. was safe, went beyond mere descriptive puffery and was a material factor in patients choosing a DEPUY SIGMA P.F.C. and/or choosing to agree to their doctor's recommendation (which was also secured by Depuy through false and misleading representations beyond the FDA-approved labeling) to undergo knee replacement surgery using a DEPUY SIGMA P.F.C. .

211. Had Depuy been truthful in its statements to patients, and included material information that it actually omitted, patients would not have chosen the DEPUY SIGMA P.F.C. and would have chosen a safer option, including but not limited to total knee replacement devices and/or total knee replacement devices using ceramic materials.

212. Depuy made voluntary statements outside the FDA-approved labeling to surgeons and the medical community about the safety of the DEPUY SIGMA P.F.C. . These statements both explicitly and implicitly conveyed the message the DEPUY SIGMA P.F.C. was safer, was safer than other metal-on- metal devices, was safer than total knee replacement, and was safer than ceramic knee devices. None of those statements were true, and had Depuy made true statements and included material information that it had omitted regarding the safety of the DEPUY SIGMA P.F.C. , surgeons would not have recommended to their patients, including Plaintiffs, that they undergo knee replacement using the DEPUY SIGMA P.F.C. . Further, Depuy provided information from sources that, over time, published new and updated information. Depuy failed to provide this new and updated information which cast doubt or definitively proved that the DEPUY SIGMA P.F.C. and all metal-on-metal knees was not safe.

All of these voluntary statements and representations went beyond the information included in the FDA-approved labeling.

213. Defendant disseminated this false information, as referenced above, to physicians, the medical community, and the public with the intention to deceive physicians and their patients and to induce the physicians to prescribe the DEPUY SIGMA P.F.C. product. These misrepresentations violated Defendant's obligations pursuant to 21 C.F.R. § 201.6(a).

214. Plaintiffs and/or Plaintiffs' physicians did in fact reasonably rely on Defendant's negligent misrepresentations, as Defendant intended. Specifically, Plaintiffs would have never had the DEPUY SIGMA P.F.C. product implanted had they been aware of the falsity of the representations specifically delineated in the preceding paragraphs

215. Defendant knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

216. Had Defendant exercised ordinary care, and complied with the then existing standards of care, Plaintiffs would not have been injured.

217. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Depuy Sigma Knee and, Plaintiff was implanted with the Depuy Sigma Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

218. As the direct and proximate result of Depuy US, Inc.'s negligence, the Plaintiff sustained severe and permanent physical injury, suffered and continues to suffer great pain of

body and anguish of mind, required extensive hospital care and treatment, incurred medical expenses, lost time from work, loss of value to pension; Ms. Woodfield required a revision surgery and continues to experience issues with her second knee revision due to the failed first knee revision; and her ability to engage in normal and usual activities has been adversely affected.

WHEREFORE, plaintiff, TERI ARCOREN, demands judgment against defendant The Depuy Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT III
NEGLIGENT MISREPRESENTATION

219. Plaintiff incorporates by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

220. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

221. Defendant had a duty under the laws of the individual states and a parallel federal duty as described above to accurately and truthfully represent to the FDA, medical community, Plaintiffs, and the public the facts about the safety of the DEPUY SIGMA P.F.C. . Instead, the representations made by Defendant were false, misleading, omitted material information or otherwise left a false impression about the safety of the DEPUY SIGMA P.F.C. as described in detail above.

222. Depuy consistently under-reported and withheld information about the likelihood of the DEPUY SIGMA P.F.C. to fail and cause injury and complications, and has misrepresented the efficacy and safety of the DEPUY SIGMA P.F.C. products, actively misleading the FDA, medical community, patients, the public at large, and Plaintiffs.

223. Defendant knew, and continues to know, that its disclosures to the public (including statements made outside the labeling) and Plaintiffs were and are incomplete and misleading and that Defendant's DEPUY SIGMA P.F.C. products were and are causing numerous patients severe injuries and complications. Depuy suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

224. As a result, Depuy , through its voluntary statements made outside the labeling as described in detail above, negligently misled and continues to mislead the public, including the medical community, health care providers, and patients, into believing that the Defendant's DEPUY SIGMA P.F.C. products were and are safe and effective, leading to the prescription for and implantation of the DEPUY SIGMA P.F.C. products into patients such as Plaintiffs.

225. Depuy failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Defendant's DEPUY SIGMA P.F.C. products. As compared to Depuy 's DEPUY SIGMA P.F.C. products, feasible and suitable alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the knee joint and similar other conditions have existed at all times relevant.

226. Depuy 's DEPUY SIGMA P.F.C. products were at all times utilized and implanted in a manner foreseeable to Defendant. Depuy failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing Defendant's DEPUY SIGMA P.F.C. products, thereby increasing the sales of the DEPUY SIGMA P.F.C. products, and also leading to the dissemination of inadequate and misleading information to patients.

227. Depuy 's failure to comply with the above-stated duties is evident through the non-exhaustive facts detailed above of malfeasance, misfeasance, and/or nonfeasance on the

part of Defendant. Subsequently, the DEPUY SIGMA P.F.C. system implanted in Plaintiffs' knees failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs, as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

228. Plaintiffs are pursuing this parallel state common law claim for negligent misrepresentation based upon Depuy 's violations of the applicable federal regulations as described above, or based on acts and omissions by Depuy that are not explicitly or impliedly preempted by federal law. 466. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendant negligently and carelessly represented to Plaintiffs, their health care providers, and the general public that certain material facts were true.

229. The representations include, in addition to the detailed allegations above, the following:

a. That the DEPUY SIGMA P.F.C. products were safe, fit, and effective for use, and were in fact, superior to a traditional knee replacement for patients;

b. That the DEPUY SIGMA P.F.C. products were safer and more effective than other available metal knee replacements on the market;

c. That the DEPUY SIGMA P.F.C. products post-market were not found to have any increased risks of device failures or complications, and enjoyed a "survival" rate as high as 94.4 percent over ten years;

d. That the DEPUY SIGMA P.F.C. was safe.

230. These misrepresentations, among others alleged herein, were made by Defendant with the intent to induce Plaintiffs and their physicians to prescribe and implant the DEPUY SIGMA P.F.C. product.

231. At the time of Defendant's misrepresentations and omissions, Plaintiffs and their physicians were ignorant of the falsity of the statements and believed them to be true.

232. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

233. All of the aforementioned information and representations emanated from the same source, Depuy and was vetted by its copy review department (or equivalent) to ensure uniformity and harmony of the marketing message. The manner by which such information and representations were distributed, made available, or otherwise provided by Depuy to Plaintiffs and their health care providers was the same and include, but are not limited to, the following: reports, press releases, advertising campaigns, product information, instructions for use and other labeling materials provided with the SIGMA P.F.C. KNEE products, print advertisements, commercial media containing material representations, as well as through their officers, directors, agents and representatives, including the Depuy sales representatives that met with, detailed, and instructed Plaintiffs prescribing and implanting physicians on the SIGMA P.F.C. KNEE products, the applications and reports by Depuy to the FDA for the SIGMA P.F.C. KNEE products, patient brochures, training seminars hosted by said Defendant, CME materials created and distributed by Depuy , information supplied at professional conferences at booths hosted or manned by Depuy , or their Key Opinion Leaders, as well as the websites of Depuy that provided

information on the SIGMA P.F.C. KNEE products including product description, indications for use, instructions for use, and ordering information.

234. Prior to, on, and after the dates Plaintiffs and their physicians purchased and used the SIGMA P.F.C. KNEE products, said representations were untrue at the times they were made, and there was no reasonable ground for Depuy to believe said representations were true when said Depuy made said representations. And to the extent Depuy did not know representations were untrue, when Depuy learned the representations were not true, it failed to correct the record and update the medical community on the truth, leaving a false impression about the safety of the SIGMA P.F.C. KNEE due to Depuy 's failures to communicate.

235. Prior to, on, and after the dates Plaintiffs' and their physicians purchased and used the SIGMA P.F.C. KNEE products, Depuy intended that Plaintiffs' and their physicians, and the general public would rely on said representations and prescribe and implant the SIGMA P.F.C. KNEE products, which did in fact occur.

236. Prior to, on, and after the dates during which SIGMA P.F.C. KNEE products purchased and used the device, Depuy intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

237. Depuy knew or should have known prior to introduction on the market and at the time of submitting its PMA applications that these representations were untrue, from their own internal testing, analysis and investigation throughout the design and manufacturing process.

238. Moreover, post-market performance promptly revealed poor outcomes in patients who were suffering failures and adverse events at an increased rate compared to other knee replacement devices. This triggered the obligation for further investigation and analysis of the safety and efficacy of the Sigma P.F.C. Knee product from Depuy , which further confirmed

that the Sigma P.F.C. Knee products were, in fact, inferior in safety and efficacy and posed greater risks of harm and death than other knee replacement products on the market.

239. It was known or should have been known by Depuy , at all relevant times, that the SIGMA P.F.C. KNEE products, by way of their less invasive design, created and caused these devices to be more apt to fail; indeed, SIGMA P.F.C. KNEE products were found to occur at a significantly increased rate compared to other Knee replacement products. This information was revealed in said Defendant's pre-market testing and analysis, and has been reaffirmed throughout the post-market experience of these products, as reflected by the increased number of these adverse event reports by physicians and published opinions in medical literature.

240. Depuy owed a duty in all their undertakings, including the dissemination of information concerning its SIGMA P.F.C. KNEE products, to exercise reasonable care to ensure that they did not in those undertakings create unreasonable risks of personal injury to others.

241. As set forth above Depuy disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of SIGMA P.F.C. Knee device with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendant's SIGMA P.F.C. KNEE products.

242. Depuy , as a medical device designer, manufacturer, seller, promoter and/or distributor, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using SIGMA P.F.C. KNEE products, would rely upon information disseminated and marketed by Defendant to them regarding the SIGMA P.F.C. KNEE products, including information outside the labeling.

243. Depuy failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of

SIgma P.F.C. Knee device was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

244. Depuy , as a medical device designer, manufacturer, seller, promoter and/or distributor, also knew or reasonably should have known that patients receiving SIgma P.F.C. Knee device as recommended by health care professionals in reliance upon information disseminated by Defendant as the manufacturer/distributor of Defendant's SIGMA P.F.C. KNEE products would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, metallosis, increased chromium and cobalt levels, and additional surgery.

245. Depuy had a duty to promptly correct material misstatements Defendant knew others were relying upon in making healthcare decisions. Defendant purposely chose not to, however, in order to maintain their market share and level of competition with other knee device manufacturers.

246. Defendant failed in each of these duties by misrepresenting to Plaintiffs, their implanting physicians, and the medical community in general, the safety and efficacy of SIGMA P.F.C. Knee device and failing to correct known misstatements and misrepresentations.

247. In sum, Depuy for years made voluntary statements outside the labeling and directly to patients, including Plaintiffs, that the SIGMA P.F.C. KNEE was safe. This message was delivered explicitly and implicitly, was designed to convey that the SIGMA P.F.C. KNEE was safe, went beyond mere descriptive puffery and was a material factor in patients choosing a SIGMA P.F.C. KNEE and/or choosing to agree to their doctor's recommendation (which was also secured by Depuy through false and misleading representations beyond the FDA-approved labeling) to undergo knee replacement surgery using a SIGMA P.F.C. KNEE.

248. Had Depuy been truthful in its statements to patients, and included material information that it actually omitted, patients would not have chosen the SIGMA P.F.C. KNEE and would have chosen a safer option, including but not limited to total knee replacement devices and/or total knee replacement devices using ceramic materials.

249. Depuy made voluntary statements outside the FDA-approved labeling to surgeons and the medical community about the safety of the SIGMA P.F.C. KNEE. These statements both explicitly and implicitly conveyed the message the SIGMA P.F.C. KNEE was safer, was safer than other metal-on- metal devices, was safer than total knee replacement, and was safer than ceramic knee devices. None of those statements were true, and had Depuy made true statements and included material information that it had omitted regarding the safety of the SIGMA P.F.C. KNEE, surgeons would not have recommended to their patients, including Plaintiffs, that they undergo knee replacement using the SIGMA P.F.C. KNEE. Further, Depuy provided information from sources that, over time, published new and updated information. Depuy failed to provide this new and updated information which cast doubt or definitively proved that the SIGMA P.F.C. KNEE and all metal-on-metal knees was not safe. All of these voluntary statements and representations went beyond the information included in the FDA-approved labeling.

250. As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

WHEREFORE, plaintiff, TERI ARCOREN, demands judgment against the Depuy Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT IV
NEGLIGENCE PER SE

251. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

252. Defendant had a duty to exercise reasonable care and comply with existing standards in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of Depuy Sigma P.F.C. Knee product, and post-market vigilance regarding same, and to comply with the terms of the PMA.

253. Defendant failed to exercise reasonable care and failed to comply with existing laws in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of the Depuy Sigma P.F.C. Knee product, and post-market vigilance regarding same, and by failing to comply with the terms of the PMA.

254. Under federal law governing labeling for the Depuy Sigma P.F.C. Knee product, Defendant was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e) (amended and recodified on June 30, 2006 at 21 C.F.R. § 201.80(e)), for devices approved before June 30, 2001, including The Depuy Sigma P.F.C. Knee product). Defendant also was required to list adverse reactions that occurred with other products in the same class as the Depuy Sigma P.F.C. Knee product. *Id.* at § 201.57(g) (re-codified on June 30, 2006 at 21 C.F.R. § 201.80(g), for drugs approved before June 30, 2001). Breaches of these duties constitute independent acts of negligence under state law

255. Defendant failed to exercise reasonable care and violated 21 U.S.C. §§ 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.80, and 201.128, in particular. The violations constitute independent violations of state negligence law.

256. The DEPUY SIGMA P.F.C. KNEE was misbranded under federal law as described above. The laws, regulations and terms of the PMA violated by Defendant were designed to protect Plaintiffs and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, Defendant's conduct constitutes negligence per se.

257. Defendant knew or should have known that consumers, such as Plaintiffs and their minor children, would foreseeably suffer injury as a result of Defendant's failures to exercise reasonable care, as set forth above.

258. Defendant's negligence was the proximate cause of Plaintiffs' harm, and economic loss, which Plaintiffs suffered and/or will continue to suffer.

259. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs suffered physical pain, additional surgeries, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

COUNT V
BREACH OF EXPRESS WARRANTY

260. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

261. The Depuy Defendants advertised, labeled, marketed and promoted the Depuy Sigma Knee, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use,

262. More specifically, Depuy Defendants represented that the Depuy Sigma Knee was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

263. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

264. The Depuy Sigma Knee did not conform to the representations made by Defendants in that the Depuy Sigma Knee was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

265. At all relevant times, Plaintiff used the Depuy Sigma Knee for the purpose and in the manner, which was reasonably foreseeable to Defendants.

266. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

267. The breach of the warranty was a substantial factor in bringing about Plaintiff injuries.

268. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Depuy Sigma Knee, Plaintiff was implanted with Depuy Sigma Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, plaintiff, TERI ARCOREN, demands judgment against Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT VII
BREACH OF IMPLIED WARRANTY

269. Plaintiff repeats and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

270. The Depuy Sigma Knee was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Depuy Sigma Knee minimally safe for its expected purpose.

271. At all relevant times, Plaintiff used the Depuy Sigma Knee for the purpose and in the manner intended by Defendants.

272. Defendants sold the Sigma device for plaintiff's ultimate use.

273. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

274. Defendants impliedly warranted to Plaintiff and her physicians that the Sigma device was safe and of merchantable quality and for the ordinary purpose for which the product was intended and marketed to be used.

275. The alleged defects existed at the time the Sigma device left the Depuy Defendant's possession.

276. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Sigma device was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as they were marketed and intended to be

used. Specifically, at the time Plaintiff and her physicians purchased and used the devices, the products were not in a merchantable condition in that:

a. The Sigma device offered no benefit to patient outcomes,

b. The Sigma device suffered from unreasonably high loosening and revision rates.

277. The breach of the warranty was a substantial factor in bringing about Plaintiff injuries.

278. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Depuy Sigma Knee, Plaintiff was implanted with Depuy Sigma Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, plaintiff, TERI ARCOREN, demands judgment against Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages available by law or statute in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages paid or owed by Plaintiff in an amount to be determined at trial of this action;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants, which constitute gross negligent, as Defendants demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Prejudgment interest;

5. Post-judgment interest;

6. Awarding Plaintiff the costs of these proceedings; and

Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demand a trial by jury as to all claims in this action.

Dated: November 14, 2022

Napoli Shkolnik, LLC

By: /s/ Nicholas R. Farnolo

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